K121679

Roche

OCT 11 2012

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
Contact Person: Mike Flis
Date Prepared: 11 October 2012

2) Device name

ACCU-CHEK Inform II Blood Glucose Monitoring System consisting of:

- Meter: ACCU-CHEK Inform II Meter
- Test Strip: ACCU-CHEK Inform II Test Strip
- Controls: ACCU-CHEK Inform II Control Solutions
- Linearity Kit: ACCU-CHEK Inform II Linearity Test Kit

Common name: whole blood glucose test system
Classification name: Glucose dehydrogenase, glucose (21 C.F.R. § 862.1345)
Product Codes: LFR, Glucose Dehydrogenase
JJX, Single (specified) analyte controls (assayed and unassayed)

3) Predicate device

The ACCU-CHEK Inform System presented in k003846 is the predicate for the ACCU-CHEK Inform II system.

The controls solutions presented in the ACCU-CHEK Aviva 510(k) submission (k043474) are the predicate for the ACCU-CHEK Inform II control solutions.

The Nova StatStrip Glucose Linearity Kit (receiving clearance in k060345) is the predicate for the ACCU-CHEK Inform II Linearity Kit.

Continued on next page

4) Device Description

The ACCU-CHEK Inform II System includes the following components and accessories: Meter, Code Key Reader, Base Unit (with power supply) test strips, and controls.

When an ACCU-CHEK Inform II test-strip is inserted into the ACCU-CHEK Inform II meter, a small alternating current (AC) is applied until the application of blood causes a spike in the conductivity to be observed at the measurement and sample-sufficiency electrodes – both are used to assure an adequate sample has been applied.

The instrument then applies a series of AC voltages at four frequencies and reads the AC responses. These carry information about the sample type and environmental temperature; they also allow the system to perform various internal quality checks.

After the AC measures are completed, a small (DC) voltage is applied and current is observed which is proportionate to the glucose. The AC and DC information are then combined to provide a hematocrit and temperature compensated glucose result.

ACCU-CHEK Inform II System is the first point-of-care glucose meter featuring wireless connectivity functionality. Unlike the predicate device, ACCU-CHEK Inform II meter has the capability of direct data transfer right after each measurement, thus ensuring actual patient data to appear on the doctor's desk shortly after these data have been created at the bedside. It is understood that a transfer of data can only occur, when a stable communication with the Data Management System has been built up by the devices before transfer of data.

The glucose meter system has been designed in a way that its connectivity feature is virtually invisible to the operator. Only the appearance of an icon at the lower edge of the touch screen display indicates potential radio frequency activity to allow new information on control material or strip code files to be downloaded.

Even when there is no wireless WLAN available, the ACCU-CHEK Inform II meters work fine as long as the necessary information like operator list, strip code, and control lot is available. The device can store as many as 2000 measurement results in its memory which will be transferred as soon as there is a stable connection to the WLAN and no measurement operation pending.

Continued on next page

510(k) Summary, Continued

5) Intended use

ACCU-CHEK Inform II System

The ACCU-CHEK Inform II Test strip are for use with the ACCU-CHEK Inform II meter to quantitatively measure glucose (sugar) in venous whole blood, arterial whole blood, neonatal heelstick, or fresh capillary whole blood samples drawn from the fingertips as an aid in monitoring the effectiveness of glucose control. The system is not for use in diagnosis or screening of diabetes mellitus, nor for testing neonate cord blood samples.

The ACCU-CHEK Inform II Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings. This system should only be used with single-use, auto-disabling lancing devices.

The multiple-patient use ACCU-CHEK Inform II Blood Glucose Monitoring System will consist of:

- Meter: ACCU-CHEK Inform II Meter
- Test Strip: ACCU-CHEK Inform II Test Strip
- Controls: ACCU-CHEK Inform II Control Solutions

The ACCU-CHEK Inform II Controls are intended for quality control performance checks on the ACCU-CHEK Inform II system with ACCU-CHEK Inform II test strips.

The ACCU-CHEK Inform II Linearity Test Kit is intended for use for periodic verification of linearity of the ACCU-CHEK Inform II system using ACCU-CHEK Inform II test strips.

6) Substantial equivalence

The ACCU-CHEK Inform II Test System is substantially equivalent to the ACCU-CHEK Inform Test System.

Continued on next page

510(k) Summary, Continued

7) Data demonstrating substantial equivalence

Performance testing on the ACCU-CHEK Inform II System demonstrated that the device meets the performance requirements for its intended use. The data demonstrates that the test strip is substantially equivalent to the predicate device.

	ACCU-CHEK Inform II System	ACCU-CHEK Inform II System ISO 15197:2003	ACCU-CHEK Inform (predicate)
Arterial Blood Samples	N = 214 y = 1.038x – 3.5 r = 0.990 Range = 58 to 322 mg/dL HCT range = 19 to 54%	100% of glucose results fit within accuracy requirement limits	N = 143 y = 1.045x – 1.3 r = 0.984 Range = 75 to 388 mg/dL
Capillary Blood Samples	N = 200 y = 1.018x – 3.4 r = 0.980 Range = 22 to 572 mg/dL	100% of glucose results fit within accuracy requirement limits	N = 187 y = 0.991x + 8.4 r = 0.980 Range = 41 to 503 mg/dL
Neonate Capillary Blood Samples	N = 191 y = 1.011x + 1.5 r = 0.976 Range = 28 to 152 mg/dL HCT range = 23 to 58%	99.4% of glucose results fit within accuracy requirement limits	N = 105 y = 0.999x – 4.4 r = 0.981 Range = 33 to 153 mg/dL HCT Range = 30 to 64%
Neonate Cord Blood Samples	Not claimed	Not claimed	Same as above
Venous Blood Samples	N = 439 Y = 1.01x -2.2 R = 0.995 Range = 38-546 mg/dL HCT range = 20-63%	100% of glucose results fit within accuracy requirement limits	N = 218 y = 0.975x + 3.0 r = 0.987 Range = 41 to 503 mg/dL
Precision	Repeatability and reproducibility studies show a variation from strip to strip ≤ 3.4%	Not applicable	Repeatability and reproducibility studies show a variation from strip to strip ≤ 3.2%
Consumer User Performance Evaluation	N = 174 Y = 0.933x + 6.6 R = 0.990 Range = 56-579 mg/dL	98.9% of glucose results fit within accuracy requirement limits	N = 187 y = 0.985x + 7.5 r = 0.977 Range = 41 to 503 mg/dL
Measuring Range	10-600 mg/dL	---	10- 600 mg/dL
Measuring Time	5 seconds	---	5 seconds
Sample Volume	0.6 µL	---	0.6 µL
Hematocrit Range	10-65%	---	20-65% for glucose <200 mg/dL 20-55% for glucose >200 mg/dL

7) Data demonstrating substantial equivalence, continued

The ACCU-CHEK Aviva control solutions (receiving clearance in k043474) are the predicate control solutions for the ACCU-CHEK Inform II control solutions. Below is a comparison of the ACCU-CHEK Inform II control solutions to the predicate, and the regulation numbers and product codes have been included.

	ACCU-CHEK Inform II Control Solutions (k121679)	ACCU-CHEK Aviva Control Solutions (k043474)
Intended Use Statement	For performance checks on the ACCU-CHEK Inform II system with ACCU-CHEK Inform II test strips.	For performance checks on the ACCU-CHEK Aviva system with ACCU-CHEK Aviva test strips
Classification Regulation	862. 1660	862. 1660
Product Code	JJX	JJX
Analyte	Glucose	Glucose
Number of Solutions	2 Levels	2 Levels
Low Level Target	45 mg/dL	45 mg/dL
High Level Target	307 mg/dL	307 mg/dL

7) Data demonstrating substantial equivalence, continued

The Nova StatStrip Glucose Linearity Kit (receiving clearance in k060345) is the predicate for the ACCU-CHEK Inform II Linearity Kit. Below is a comparison of the ACCU-CHEK Inform II Linearity Kit to its predicate, and the regulation numbers and product codes have been included.

	ACCU-CHEK Inform II Linearity Kit (k121679)	**Nova StatStrip Glucose Linearity Kit (k060345)**
Intended Use Statement	For periodic verification of linearity of the ACCU-CHEK Inform II system using ACCU-CHEK Inform II test strips.	Nova StatStrip Glucose Linearity Kit solutions are used to check the linearity of the Nova StatStrip Glucose Hospital System.
Classification Regulation	862. 1660	862. 1660
Product Code	JJX	JJX
Analyte	Glucose	Glucose
Number of Solutions	6 Levels	5 Levels
Low Level Target	28 mg/dL	31 mg/dL
High Level Target	559 mg/dL	514 mg/dL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 20, 2012

Roche Diagnostics
c/o Mike Flis
9115 Hague Road
Indianapolis, Indiana 46250

Re: k121679
Trade Name: Accu-chek Inform II blood glucose monitoring system
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, LFR, JJX
Dated: September 19, 2012
Received: September 21, 2012

Dear Mr. Flis:

This letter corrects our substantially equivalent letter of October 11, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson

for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Indications for Use Statement

510(k) Number (if known): k121679
Device Name: ACCU-CHEK Inform II Blood Glucose Monitoring System

The ACCU-CHEK Inform II Test strip is for use with the ACCU-CHEK Inform II meter to quantitatively measure glucose (sugar) in venous whole blood, arterial whole blood, neonatal heelstick, or fresh capillary whole blood samples drawn from the fingertip as an aid in monitoring the effectiveness of glucose control. The system is not for use in diagnosis or screening of diabetes mellitus, nor for testing neonate cord blood samples.

The ACCU-CHEK Inform II Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings. This system should only be used with single-use, auto-disabling lancing devices.

The ACCU-CHEK Inform II Controls are intended for quality control performance checks on the ACCU-CHEK Inform II system with ACCU-CHEK Inform II test strips.

The ACCU-CHEK Inform II Linearity Test Kit is intended for use for periodic verification of linearity of the ACCU-CHEK Inform II system using ACCU-CHEK Inform II test strips.

Prescription Use ___XX___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___XX___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k121679